IDENTIFYING TECHNOLOGY(IES) FOR CLINICAL RESEARCH POST-COVID-19

by

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Abstract

Clinical research aims to understand diagnostic methods, diseases, and new treatments or medical devices that can advance patient care. The COVID-19 pandemic in 2020, a respiratory disease caused by SARS-CoV-2, impacted clinical research units in healthcare and brought new perspectives on how to better the future of clinical research by adopting modern technology. Clinical research has encountered much advancement over the years, with technology being the primary factor that accelerates clinical research growth. Incorporating new technology in clinical research translates to increased productivity and efficacy in patient engagements, trial management, novel outcomes, and reduced patient burden. The application of new technology in clinical research and next-generation clinical trials can be made effectively with lower costs and more accurate data. In this paper, an in-depth literature review was done to evaluate and discuss how the COVID-19 pandemic brought new transformations to clinical research and how the incorporated technology will transform in the future to optimize patient care. Many remote technologies were deployed, such as eConsent, home care visits, and direct drug delivery, resulting in better data collection and saving time and resources.

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Chapter 1

1. Introduction

1.1. Background

Clinical research is an integral aspect of healthcare because it promotes the development of new interventions aimed at addressing identified health issues. The National Institute of Health (NIH) defined clinical research as one that involves human subjects and utilizes materials from human subjects such as samples of their tissues or behavior. It is vital in the development of new pharmaceutical drugs. The drug development process entails pharmacological and pharmacodynamic studies of the product to observe any potential side effects it may have on patients[1]. The process includes studying human subjects' reactions to the product, the absorption, distribution, metabolism, excretion (ADME) of the investigational product, and its safety and efficacy. The knowledge derived from clinical research is utilized to produce products and design processes that help prevent, diagnose, prognose, treat, and potentially cure patients of a particular condition or disease. Clinical trials are typically pursued to discover the knowledge of new treatments and behavioral interventions. The treatments usually conducted in human trials often entail assessing new novel vaccines, nutritional choices, drugs, and medical devices. The practice of clinical research has evolved as diseases become more complex and increasingly infectious, which has necessitated improved developmental processes to ensure populations' safety.

Due to the nature of clinical research, patients might be harmed, which necessitates rigorous measures to ensure their safety. Clinical research has evolved from traditional clinical methodologies to modern clinical research[2]. The trials are cautiously planned, revised, and finalized before being submitted to an ethics committee (i.e., Institutional Review Board, etc.) for

[1] National Institutes of Health (2020). What are clinical trials and studies.
[2] approaches at National Institutes of Health (2020). What are clinical trials and studies?.

approval because they involve human subjects. Anyone is allowed to participate regardless of age. Other measures adopted include the four stages of clinical research trials. Stage 1 entails identifying a safe drug dose limit and its side effects in a few people. It is usually conducted on 20 to 100 healthy research participants. Phase 2 studies test the drug's efficacy due to it being found to be safe in phase 1, and it involves more research participants (around 100 up to 300) and entails observing any harmful effects. Phase 3 evaluations are done to assess the therapeutic effect of the drug. It is conducted on larger populations, usually 300 to 3000 individuals in different regions and countries. Phase 4 studies are usually termed as post-marketing surveillance, and they take place after country approval to assess the long-term drug effects[3]. These rigorous processes ensure the safety of patients who eventually use the developed drugs. However, the complexity of diseases, especially infectious diseases, has mandated a change in the clinical research process because of researchers, clinicians, and patients' safety issues.

Particulalry, the emergence of Covid-19 disease in 2020 resulted in a new perspective in the clinical research field. According to a study by Dorn (2020), it disrupted clinical trials worldwide with long-lasting effects on medical science. The virus has severely affected the ability to conduct clinical trial research in safe and effective ways. Most clinical trials often deal with vulnerable populations who are at risk of infections from COVID-19. Thousands of non-COVID-19 trials have been halted because of government-imposed lockdowns to limit the spread of the virus. The virus has also resulted in considerable reorientation in the way that clinical research is conducted towards COVID-19. These aspects -the disruption of clinical trials and the need to adjust to the challenging environment- have reinforced the need for quick and optimized clinical trials and modern technology in clinical research practices to curb the pandemic and other diseases

[3] What are clinical Trials and Studies, 2020.

that could develop into pandemic proportions in the future through continued safe and effective clinical research and trials.

Today, thousands of COVID-19 vaccine studies are being conducted globally to develop an effective vaccine for COVID-19. The biggest problems in clinical research, which have also been revealed in the trials done during the COVID-19 clinical tests, are that they are expensive to perform, and time-consuming depending on the protocol's design. The Coronavirus is risky for both patients and scientists (the risk of infection is high). Clinical trials naturally take a long time to complete and require many participants' continuous monitoring. The government imposed lockdowns and patients isolation measures have created challenging environment for conducting clinical trials. Besides, many organizations rely on an archaic way of documenting information via paper. Although technology is proliferating in this era, it is not fully utilized in clinical trial settings because stakeholders have been slow to embrace new changes[4]. The inertia to integrate technology into clinical research trials is now being felt as the COVID-19 ravages the public and threatens entire nations' well-being. However, the race and need to develop an effective vaccine has never been more dire. The challenge is how technology could help address the clinical research process under such challenging conditions to manage the COVID-19 pandemic effectively.

1.2. Statement of the Problem

Although the purpose of clinical research and trials in improving the quality of patient care has been discussed thoroughly in the literature, technology's role has not been fully explored. The study by Aimee (2015) revealed that one of the key factors for the sluggish adoption of e-technology in clinical research is the limited empirical evidence on whether these technologies enhance or improve the design of clinical trials. Moreover, there is limited information about the

[4] Brucher, L., Duprel, C., Georges, A., Kilders, Y. (2020). Digitalization of clinical trials.

type of technologies that could facilitate clinical research trials from onboarding participants, collecting data, and monitoring patients under study. Clinical trials' goal is to assess new experiments and treatments and identify their side effects on patients[5] . The process involves participants in different sites, all with different conditions. Another significant factor for the sluggish integration of technology into clinical research is the lengthy regulatory requirements that delay the planning and commencement of clinical research activities. Before a participant enrolls in a clinical trial, they must undergo an informed consent process where they are informed fully about the study's purpose, the risks involved, the benefits, the length of the study, and what happens during the study. With the COVID-19 pandemic, these processes have been largely hampered as lockdowns and isolation strategies (social distancing) take root to limit rates of infections. Clinical researchers continue to grapple with issues like difficulties in structuring and prioritizing research questions, how to observe the ethical considerations diligently, and the challenge of globalizing clinical trials (Rosa, Campbell, Miele, Brunner, & Winstanley, 2015). Incorporating modern technology and utilizing it to optimize clinical research is also a challenge in clinical. Understanding how technology could facilitate and fast-track clinical process is vital in helping stakeholders address the challenges faced during the COVID-19 pandemic. The information could also promote sustainable and quality clinical research in the future.

1.3. Research Questions

In light of the Covid-19 pandemic, pre-existing clinical research technologies are being forcibly thrust into the working environment that many were not designed for. In enhancing future clinical research, how could new technologies function according to ethical regulations and perform quality clinical research while minimizing deviations caused by human error?

[5] What are Clinical Trials and Studies, 2020.

Research Objectives

1. To understand the key concepts in clinical research, such as recruitment and protection of human subjects and how new technologies and software could improve the process.

2. To evaluate the impact of COVID-19 on future clinical research.

3. To evaluate the impact of incorporating modern technology in the future of clinical research.

4. To identify a focus for future clinical research.

1.4. Background and Significance of Problem

Clinical research participants often volunteer for clinical trials and bear the associated risks without any guarantee for direct benefits. The COVID-19 pandemic presents significant challenges in addition to these risks, including the safety of researchers. Clinical trials have been the premier method for testing and validating new drugs and therapies. The approval of such medicines is based on successful trials in their safety and efficacy. The growing pressures on the clinical research processes during the COVID-19 pandemic coupled with the risks involved call for the integration of technologies that will help minimize the challenges and fast track the development of new drugs and therapies. Safety, accurate data collection, and proper participant monitoring are critical to successful clinical trials during such times.

The FDA has long warned against clinical research trials that put the participants at risk and poor compliance with approved research protocols. Drawing from insights from the past harms on research participants necessitates that the findings of this study be seriously considered to protect both participants and scientists given the high infection rate of the Coronavirus. Technology could help address FDA warnings such as the failure to maintain adequate and accurate case histories that record all observations and other data integral to investigations on the

efficacy of the tested drugs (Browning, 2019). The digital records generated or captured and stored in digital databases duing clinical research could be audited to identify issues such as the researchers' failure to protect the rights, safety, and welfare of the clinical trial participants, report adverse reactions to the developed drugs, or fail to provide timely treatment to participants who react adversely to the drugs. Thus, in this manner, technology could help improve compliance to set regulations, which will help increase the speed of clinical research and the timely address of medical and drug needs during the COVID-19 pandemic cycle.

Chapter 2

2. Methodology

This study design used was the qualitative design, and it entailed a comprehensive review of the literature. The literature was sourced electronically by doing an electronic search of reputable medical databases such as PubMed and Cinahl. The literature included for use in the review were published in the last five years. The timeframe was selected because it allowed the inclusion of the most recent research. The information sources were mapped using keywords and phrases. These keywords and phrases included: the scientific research process, the evolution of clinical trials, virtual clinics, and COVID-19, challenges in recruitment and retention of clinical trial subjects, use of electronic data sources in clinical trials, evaluating clinical performance, artificial intelligence technology, and medical diagnosis and prediction, and effects of COVID-19 epidemic on clinical research. The study did not include human participants, which exempted it from the IRB's requirements to protect human subjects.

The data collected was analyzed thematically to ensure consistency in reporting. It entailed coding and categorizing the data found in the selected articles. Each category was subsequently compared, and further analysis and synthesis were completed. The approach was appropriate because the data was sourced from different studies with varied methodologies. This also necessitated the use of a qualitative approach for this study and analysis of data.

The qualitative design based on a literature review was ideal because it transcends existing knowledge's strengths and weaknesses and develops a more meaningful understanding. The review was conducted to evaluate the rigor of clinical research processes, the role of technology, and how technology could be integrated into fast-track clinical research during the COVID-19 pandemic.

The goal was to summarize past research and present a current state of knowledge that calls attention to the integration of technologies into future clinical research.

2.1. Problem Formulation Stage

This section provides focus and boundaries for the literature review process by defining the research problem and interest variables. The problem addressed in this literature review was the disruption of clinical research processes following the outbreak of the COVID-19 pandemic because of the lack of supporting technologies that would facilitate safe and timely clinical research processes. Variables of interest for the project included the current state and process of clinical research and the role of technology in facilitating the process. The purpose of this scholarly project was to identify how the adoption of technology in clinical research processes could improve medical processes in the event of outbreaks, such as the COVID-19 pandemic.

Chapter 3

3. Literature Review

3.1. The Basis of Clinical Research: Planning

Studies show that the clinical research process in its current state is intensive and laborious. Weintraub (2020) revealed that the lengthy processes and need to adhere to the set regulations that govern clinical trials that involve live animals or human beings slowed down the drug development process. The study by Segelov et al. (2020) also revealed that the outbreak of the COVID-19 pandemic had hampered these clinical trial processes. To fully understand the relevance of these findings, one needs first to assess the process of clinical research. According to the Nation Institute of Health (NIH), clinical research includes patient-focused research, well-being research, epidemiological and behavioral research. Clinical research involves human subjects or utilizes the materials from human subjects, such as samples of their tissues or behavior. Most clinical research aims to study the reaction of human subjects to the investigational product, including the absorption, distribution, metabolism, and excretion of the product under study and its safety and efficacy ("What is Clinical Research?" 2020). Throughout the entirety of a clinical trial, human subjects are carefully monitored, and most times, blood samples are collected at specific intervals as defined in the clinical trial protocol. The data generated from clinical research are analyzed to determine whether the participants' reactions warrant their continued participation in the study. The end goal is to better patient care by creating new, safe, effective, and cost-effective drugs for global production. The NIH asserts that designing processes that maximize efficiency in preventing, diagnosing, treating a disease is an immense contribution toward meeting the end goal. However, few studies have investigated how to fast track this process. According to a study by Eichler and Sweeney (2018), one of the future challenges that are likely to impact clinical trials is

the lack of technologies that would aid the recruitment, monitoring of participants, collecting data, and reporting of patients' reactions remotely. Most of the studies, including Eichler and Sweeney (2018), only cite this as an issue and do not provide solutions to address it. This has resulted in a dearth of information about the technologies that would lessen the burden of conducting clinical research.

3.2. Data Collection

Another vital issue that has been identified is the collection of data, more so with the outbreak of the COVID-19 pandemic. The study by Sessler and Imrey (2015) revealed some of the critical issues that limit clinical trials' success are the study design and data collection methods. The issues include ineffective participant recruitment strategies that limit the data collection process. There is high participants' turnover and the cost implications are high. According to the NIH, clinical trials help collect data on the safety and effectiveness of products under study (What Are Clinical Trials and Studies? 2020). Clinical trials on human subjects result in the discovery of knowledge of new treatments and behavioral interventions. The experimental treatment studies in human trials usually entail assessing new novel vaccines, nutritional choices, drugs, nutritional supplements, and medical devices. To conduct clinical trials, approval from the health authority and ethics committee is essential. The approval of a clinical trial is done after evaluating the risk and benefit ratio of the trial.

Moreover, clinical trials vary in size and cost depending on the number of research participants recruited. Clinical trials happen in phases that necessitate the use of multiple trial centers, which increase the cost of conducting them. Besides, in phases one and two, twenty to three hundred research participants make the process costly[6]. Breton, Lamberti, Dion, Getz (2020)

[6] What are Clinical Trials and Studies, 2020.

also reveal that the COVID-19 outbreak has disrupted the data collection processes because of the virus's infectious nature and high fatalities for vulnerable patients. However, these studies do not explain how these challenges could be addressed, which leaves clinical researchers unable to address them in the research process.

Currently, there are limited studies on the technologies that fit the needs of different clinical trials. When classified based on purpose, clinical trials give rise to the following experiments; prevention, screening, treatment, life value, genetic, fixed trials, and adaptive clinical experiments. Prevention clinical trials involve study trials to protect people who have not contracted the disease from contracting it. The study approach involves the use of vaccines, micronutrients, vitamins, lifestyle changes, and drugs. Screening clinical trials intent to research and develop better and sustainable quality protocols for diagnosing a particular condition or disease. Treatment clinical trials aim to assess experimental drugs, new surgery or therapy approaches, and a new combination of drugs to find if it is effective in human subjects[7]. There is a need to define the technologies that could improve these different clinical trials. The current mostly manual process limits the effectiveness of these processes in the light of the COVID-19 pandemic**.** Besides, the involvement of humans and live animals in clinical research further complicates the process in the wake of the COVID-19 pandemic. The virus is spread through an infected person or contact with a contaminated surface. In clinical research, clinicians and nurses are mostly expected to be near the patients under study, which puts them at considerable risk.

Overall, the application of technology in the clinical research process will help address most of these issues. The current studies on the clinical research process do not address technology in the research process despite the numerous challenges identified and the laborious process. The

[7] What are Clinical Trials and Studies, 2020.

studies also reveal that there is also a general lack of awareness about the type of technologies that could be used to overcome the challenges caused by the COVID-19 pandemic regarding the recruitment of participants, collection of data, and reporting of patients' reactions to drugs under study.

3.3. Recruitment of Participants

The selection of study participants is also another critical issue that could be addressed using technology. Clinical trials that entail drugs are usually categorized into four phases, with each having different participant sizes. Phase 1 studies usually test the drug's harmless dosage and its side effects in a few 20 to 100 healthy research participants. Phase 2 needs more human subjects, usually 100 up to 300 participants, to observe any harmful effects. Phase 3 studies are done to assess the therapeutic effect of the drug, and it is conducted on larger populations, usually 300 to 3000 individuals and in different regions and countries. Phase 4 is typically known as the post-marketing stage, where the FDA approves a drug. At this point, it is ready to be prescribed to the public, and anyone with the condition may take it. The current approach to participant selections is randomization. It is applied in phase three trials, randomly choosing the research participants[8]. Research participants are randomly given the existing drug and the drug under investigation, making the study a double-blind clinical trial. Double-blinded trials help to eliminate bias during the interpretation of results. 25% to 30% of drugs under clinical trials proceed to phase four. Phase four clinical trial is usually termed as post-marketing surveillance and post-marketing after the country's approval to assess the drug side effects. As such, the process of drug development and testing to ensure its safety once rolled out to the public is laborious. It is prone to human errors that lengthen the experimental process and increase associated costs.

[8] Hall, K. T., & Loscalzo, J. (2019). Drug-placebo additivity in randomized clinical trials. Clinical Pharmacology & Therapeutics, 106(6), 1191-1197.

According to Kadam et al. (2016), there is a heavy burden on clinical research professionals identifying, consenting, recruiting, and enrolling a patient. Recruiting and retaining research participants is a key element for successful clinical research. Recruiting the right research participants and retaining them until the completion of the clinical trial ensures there will be a complete and accurate data set to be used and analyzed in scientific and regulatory decisions. However, clinical research professionals face the challenge of recruiting and retaining research participants (Kadam et al., 2016). Failure to recruit participants effectively and retain them until the clinical trials are finished is a major reason for the termination of clinical trials. According to the Clinical Trials Database, 55% of the trials were terminated due to a low accumulation rate (the minimum number of participants needed during a particular clinical research phase). The average enrollment efficiency of phase three and four being less than 40%[9]. Most clinical trials fail to enroll research participants within the proposed timeline, leading to the extension of the research study duration and the addition of study sites[10]. As such, the failure to recruit and retain the required number of research participants is also a major clinical trial problem. Foge (2018) also explained that the few retained participants will not answer the original research questions appropriately, which results in the delay of the study and incomplete/unevaluable data. In tackling the issue, technology benefits many clinical research professionals by saving enormous time in identifying the right patient for a study. Proper implementation of technology software could help patients by scanning electronic medical records and quickly eliminate many patients whose medical history does not meet the exact inclusion and exclusion criteria.

[9] Fogel, B.D. "Factors associated with clinical trials that fail and opportunities for improving the likelihood of success: A review" Contemp Clin Trials Commun. 2018 Sep; 11:156-164

[10] Fogel, B.D. "Factors associated with clinical trials that fail and opportunities for improving the likelihood of success: A review" Contemp Clin Trials Commun. 2018 Sep; 11:156-164

Clinical research is changing due to the advancement of health care systems. Currently, the design of clinical trials is multifaceted, refined, and modernized. These designs are put in place to find the therapy that will be useful in the treatment and management of conditions that have no treatment or those conditions that have shown little improvement with previous treatment lines. Most treatment designs utilize the inclusion criteria, which are more specific, rigorous, and tightened (Eicher et al., 2016). Inclusion criteria are intensive, leading to more prolonged recruitment, necessitating protocol modification to recruit more research participants and study sites. More than 40% of clinical research trials modify the research protocol before the first subject visit, which delays the trials by four months. Multiple studies enrolling from the same patient population may also create unanticipated competition that could slow research accrual rates. In reality, scanning through every patient's medical history is burdensome and eats up a significant amount of time. There is a need for technology that could perform a complex calculation to identify the right patient for a specific study while minimizing potential human error that could have existed when done manually.

The nature of the population influences the selection and retention of research participants. A population's education level, socioeconomic status, sociocultural understanding, and clinical research will impact the population's responsiveness to clinical trials. African Americans were the biggest victims in the Syphilis Study at Tuskegee, as they were easily misled about special free treatment and did not consent to the study. Even after treatment was found for syphilis, the study continued for several more years. As a result, the death rate was twice as high in men with syphilis[11]. As such, African Americans may not be as responsive in participating in a clinical trial due to the historical mistrust. Although the Belmont Report, which was created in 1978, provided

[11] LaMorte, W., W. (2016). Institutional Review Boards and the Belmont Principles.

three fundamental ethical principles for all human subject research, it did not erase the tragedy of systemic racism.

Clinical research study staff play a vital role in research participants' selection through research participants' involvement. Study staff is trained to understand the research protocol and effectively communicate with the patient, understand the challenges the research participant is going through, and provide encouragement to the research participants. Therefore, study staff could promote the retention of research participants, which would be a positive factor in clinical trials. For research professionals to reduce dropout among research participants, professionals should provide proper guidance and coach the research participants explaining in detail the risks of participating in trials and the risk mitigation plans. This would help reduce the dropout rate since the research participants will be aware of what they are subscribing to without pressure or coercion. For research trials that require additional visits for tests and procedures, the research investigators should provide incentives to the research participants to compensate them for the inconvenience they have been subjected to by attending additional visits (Torous et al., 2018). The clinical research study site should provide a positive environment to promote research participants' retention. The staff at the site should employ a courteous and friendly approach to the participants. By observing all these measures, the research participants' dropout rate will be minimized. Technology could help save time that could be utilized by clinical research professionals by providing a better bedside manner instead of being distracted by trying to remember which paperwork is needed and what the protocol dictates.

3.4. The Effect of COVID-19 on Clinical Trials

The new coronavirus SARS-CoV-2 (COVID-19) disease originated in Wuhan (China) in December 2019, and it spread worldwide. The disease caused many deaths, coupled with a

negative effect across all sectors globally; the healthcare system is one of the majorly affected sectors. The Coronavirus spreads through droplets, and it is highly contagious, where severe illness due to this disease demand hospital admission. The effects of COVID-19 in the health sector include the hospital measures to keep patients away from the hospital, where only patients with acute and terminal diseases like cancer and heart diseases are admitted. COVID-19 has affected the ability to conduct trials in safe and effective ways. The predisposition of the elderly to the virus has a more negative impact, especially in clinical trials, which usually rely on the elderly. Due to this pandemic, thousands of trials have been suspended due to the difficulties of conducting research studies with the lockdown in place. COVID-19 has placed much pressure on the clinical research field (Segelov et al., 2020).

In the effort to minimize research participants in visits, most of the study sites were closed. Many research participants also dropped out of the research study to take preventive measures towards the pandemic. As such, the research professionals were forced to look for other research participants. This demands the amendment of research protocol coupled with increased cost and ethical challenges. The redirection of resources to help fight the COVID-19 pandemic also imposed some challenges to the clinical research field[12].

Most governments currently have issued permission to continue with the clinical trials but with stringent adherence to the laid down protective measures. The laid down guidelines on how to conduct trials during this pandemic moment highlights the need to adapt trials to accommodate the pandemic. The guidelines also highlighted the need for the clinical research authority's flexibility in amending the protocols, deviations, and clinical data during this period. The clinical trials with the following characteristics are more likely to be delayed with this COVID-19

[12] Weintraub, K (2020). Covid-19 slows drug studies, curbs clinical trials.

pandemic; clinical trials that involve vulnerable populations as research participants have to be delayed until the pandemic is managed. Vulnerable individuals include the elderly, the immunocompromised, and patients with pulmonary diseases (Weintraub, K. 2020).

Endpoint clinical trials that need assessment in person or through hospital equipment such as CT and PET scans have to be delayed. Hospitals currently are only accessible to individuals with terminal diseases or individuals with emergency cases; the trials that utilize the hospital have to be delayed. Clinical trials that require therapy to be administered in the hospital, such as immunosuppressive therapy clinical trials have to be delayed due to the currently limited access to the hospital. Trial sites located in places with a high density of the Coronavirus disease translate to the study's delay. The clinical trial study staff and research participants cannot effectively work harmoniously to realize the study's objectives due to the prevailing COVID-19 disease[13].

The long-standing side effects of the COVID-19 disease to the clinical research field may be delayed trials due to the restrictions put in place will increase the cost of the trials. The implication of COVID-19 in clinical research will be felt in repaired documentation, clinical trial protocol amendments, data collection, and clinical trial results interpretation. The research participant's risk of contracting the COVID-19 disease is also highlighted[14]. If the patient succumbs because of the Coronavirus, the validity of the clinical trial results will be affected because of reduced the number of participants needed for an effective clinical study. Research participants who succumb are removed from the trials, and this, as much as it is not a willing dropout decision, will reduce the number of research participants. Failure to have the required number of research participants will impact the clinical trial's potential to achieve statistical

[13] Weintraub, K (2020). Covid-19 slows drug studies, curbs clinical trials.

[14] Weintraub, K (2020). Covid-19 slows drug studies, curbs clinical trials.

significance. The cost of recruiting other research participants to achieve the threshold required number is increased. The associated delays also alter clinical trial protocols[15].

Technology could act as a potential gatekeeper in avoiding human errors during a clinical trial. When a clinical trial is conducted, there is always a constant evolution to the protocol as a reaction to an event that transpired .Therefore, a protocol will always be continuously amended once it has been reviewed by the regulatory authorities like the IRB (Insitutional Review Board), DSMC (Data Safety Monitoring committee), and so on. On top of that, once a protocol is amended, other regulatory entities must be immediately informed of new changes to review and approve the change for human protection before a trial can be continued. Clinical research professionals must stay on top of all new changes, review and study what the changes entail, and apply the changes during the conduction of a trial. In reality, human power is limited, and keeping up with constant new changes is difficult – potentially causing protocol deviations and inaccurate data reporting.

New approaches to ensure that clinical research continues despite the pandemic have been put in place by most departments and organizations conducting clinical trials. Approaches to conducting remote visits for research participants are already in place. Research participants can access their stipulated clinical visits through telehealth and home-based testing and monitoring technology. The approach employed to ensure clinical research continuity despite the pandemic provides courier services to pick up and deliver the research participant sample and investigational products. The approach ensures that the lockdown measures, as well as the social distancing rules, are observed. The clinical trial research updates are made available to the research participant through telephone, email, or elect record portal home-based study (Kellar et al., 2017). The strategy to develop optimally safe approaches for the research participant was done according to

[15] Weintraub, K (2020). Covid-19 slows drug studies, curbs clinical trials.

the FDA report. FDA issued the guideline to the researchers and clinical trial sponsors that they should protect the safety and welfare of clinical trial research participants by continuing with the trials, as per the clinical study trials or discontinuing the clinical trial use of products by the research participants (Da Silva et al., 2018).

For the clinical research field, the limited resources and inadequate and incomplete data generated from halted projects will significantly impair the clinical research movement post-COVID-19. The lack of complete data may lead to poor decision making since data usually make the basis of decision making in the clinical research field. The CRO increase of pandemic possibility planning will increase the cost of conducting clinical trials post COVID-19.

3.5. Modernizing the future of Clinical Research

Modern electronic technology is an essential tool in clinical research tool (Kellar et al., 2017). Electronic technology can be utilized to determine the viability of conducting trials and patient population through powerful computing and calculation in predicting the patients that meet study participation criteria. Electronic technology can be leveraged to identify potential research participants for a specific trial, find information about the current trial, and link with resources to reach out to the desired population. Some electronic technology utilized in clinical research includes; electronic health records, payers' data, insurance databases, and social media platforms (Parab, et al., 2014). When recruiting participants through electronic technology, professional websites can disseminate information about the current or prospective clinical trials without disclosing the details. (Mc Cord et al., 2019). Artificial intelligence as a form of modern technology can also optimize clinical research through its utilization in clinical trial design, selection, and monitoring of research participants under study. Technology, when designed correctly according to the need for a clinical trial should be able to identify potential patients that

are hard to find through internal electronic medical records, social media, or other electronic advertisements. Once a patient has been correctly identified, technology could further assist the progression of a patients' well-being throughout a clinical trial via direct data reporting on an electronic platform such as EDC (Electronic Data Capture) to ensure that the patient is not injured during the trial. Sponsors typically are required to travel to a site to monitor the a patient's progression which has been recorded by clinical research professionals. In reality, this requires elaborate time planning, and scheduling and sponsors would not have direct access to crucial data 24/7. If and when a site implements proper electronic data capture software, all pertinent information would be recorded directly online and saved in a secure cloud. As a result, this method provides a much more secure pathway of accession and gives easier access for the sponsor through 24/7 access. The FDA recognizes the importance of remote monitoring and direct online documentation, which resulted in new guidelines of the Code of Federal Regulations (CFR) 21 part 11which states that all potential electronic software must be equipped with an audit trail as real-time information are recorded. They are also stamped with time, date, and the user responsible. Another avenue that was implemented from CFR 21 part 11 also includes the legality of an electronic signature in which a delegated user can sign electronically. This is a significant change for clinical research professionals as they do not have to waste time by having to sign a document with wet ink, scan the document, print it, and store it. By law, any direct source documents in the form of a physical paper must be kept in storage for at least two years. Changing the mode of documentation from paper to electronic, it saves time as well as significant cost to buy paper, run a printer, and rent a storage.

Incorporating modern technology into the clinical research field will bring forth new perspectives on how clinical trials are conducted and promote quality, up-to-date clinical research.

Electronic modern technology makes clinical research work easier by saving a considerable amount of time for all parties involved in the clinical research process. Electronic technology will help to minimize patient visits and make clinical research easy and cost-effective. Hypothetically speaking, if the regulations allow for it – virtual visits should happen. Patients wouldn't feel as pressured to come to the office to perform necessary assessment when it can be done online thus increasing engagement and compliance. The time utilized commonly by research participants to visit the clinics is reduced (Torous et al., 2018). Electronic technology can be utilized to determine the viability of conducting trials and patient population. Electronic technology can find eligible research participants for a specific trial, find information about the current trial, and link with resources to reach out to the desired population. Some Electronic technology utilized in clinical research includes electronic health records, insurance databases, and social media platforms. When recruiting participants through electronic technology, professional websites can disseminate information about the current or prospective clinical trials without disclosing the details. Financially speaking, virtual visits saves money for both sponsors and patients as patients would not have to waste time and money for transportation, and sponsors would not be pressured to offer stipends to get patients interested in a clinical trial.

Technology has also increased patient participation and helped them feel more involved in the research process (Torous, et al., 2018). Modern technology will help curb the traditional method limitations, including the cost and time spent designing the study, including the research participants' selections and analysis and interpretation of results. Adopting modern technology will improve the clinical trials' efficiency and productivity, thus enabling optimal clinical research, and the aftermath is improved and quality patient care.

The new technology that can be adopted in clinical research includes wearable devices, virtual clinics, and remote monitoring. These modern technologies adopted in clinical research are vital since they aim to make clinical trials patient-centered (Lee et al.,2018). Ensuring that modern technology incorporated into clinical research yields optimum results, social media can provide increased opportunities for patient engagement. The 21st century have changed the way people live, and most people have some form of electronic devices that regularly connects them to the world. Clinical research stakeholders should recognize this and capitalize on the patients' time in participating for a clinical trial. Wearable devices can provide clinical trials researchers with a clear and detailed outlook of participant well-being by taking all research participant exposures and how they affect research participant well-being. It offers detailed information on the impact environment has on the research participant's treatment. Incorporating new technology in clinical research translates to increased productivity and participant engagements, trial management, novel outcomes, and reduced patient burden. Through applying the new technology in clinical research, next-generation clinical trials can be done effectively with low cost and high-quality data.

The assessment of activity and behavior of clinical research participants is one method that enables the collection of detailed and frequent information. The use of modern technology in research participants' responses measurements is relatively cheap compared to traditional methods that entail participants coming to the office for a quick survey. Besides, it captures all the information which cannot be captured in traditional clinical trial measurement methods that is done on paper. Miniature and more sophisticated sensors could provide the increased use of these technologies in clinical research trials. Sensors are used to develop digital signatures that characterize different research participants' responses and pave the way for timely interventions (Lee et al., 2018).

Technology can be utilized in clinical research to match prospective research participants in a proposed clinical trial. The devices that allows for remote access and virtual visits make clinical trials easy since they enable researchers to reach a much wider audience than they could in traditional methods. Clinical trials involving a small number of research participants can be carried out successfully through technology. Phones with apps utilized during trials are offered to the research participants to enable follow up during the study period. Patient enrollment on time is increased by 50 percent, and there is a generation of a diverse pool of participants and insightful clinical endpoints (Torous et al.,2018).

Electronic health records (EHR) are instantaneous digital records comprising patient diagnoses, medications, laboratory examinations, prescribed drugs, and clinical encounters. EHR-based clinical data plays a vital role in clinical trials. EHR is utilized by researchers in planning and designing clinical trials, site start-up, study execution, data collection, determination of trial representativeness, and clinical events follow-up (Cowie et al., 2017). Electronic health records data can pinpoint the effect of inclusion/exclusion criteria on the research study participants' recruitment rates at the site level more accurately by highlighting certain patients that has all the conditions listed on the inclusion/exclusion list. Researchers use electronic health records data to determine the phenotype of clinical research study populations. Clinical research trial sites and health systems with many prospective participants can be identified by analyzing electronic health systems data. Electronic health records data can inform the trial sample size and statistical testing considerations in clinical trials. Electronic health records data are changing how clinical trial procedures are planned and polished.

Electronic Health Monitoring is another aspect of modern technology integration into clinical research. Electronic health monitoring enables researchers to collect data on research

participants without incurring extra costs (Ellar et al.,2017). An example of electronic health monitoring in clinical research is the Apple company earbuds, which observe the research participant's vital signs. Clinical researchers can utilize this to monitor the research participants' responses to the products under trial (Philip et al., 2017). The earbuds observe the research participant's heart rate and other vital signs, and this is vital in clinical trials in remote monitoring. Besides the earbud, various applications and devices in the market are capable of tracking heart rate, blood pressure, and other vital signs. These applications are vital to clinical researchers since the data obtained can be analyzed and used based on clinical research trials. The applications have the advantage of enabling researchers to access data with minimal costs since the regular visits to the site to collect data are minimized. The challenge posed by the monitoring devices and applications to the clinical researchers is the standardization of different types of devices and applications.

The future success and efficiency of clinical research and clinical trials are heavily dependent on the utilization of emerging technology. The technology to be incorporated in the future should promote immersed treatment to the clinical trials patients (immerse treatment entails gathering data that allows researchers to help participants overcome worries or concerns that might limit the study process), facilitate continuous patient data collection, allow researchers to ensure that adaptable trials are in place, and support the next-gen support ecosystems. Immersed treatment entails the use of technology to offer therapeutic solutions with minimal pain. Clinical trials usually accompanied by painful procedures and medications usually face high rated research participants' noncompliance. By integrating the technologies that ensure research participants encounter minimal or no pain during the trials, the quality, efficiency, and productivity of research will increase (Ellar et al.,2017).

Ensuring that modern technology incorporated into clinical research yields optimum results through social media since social media provides increased opportunities for patient engagements. Incorporating new technology in clinical research translates to increased productivity and efficacy in patient engagements, trial management, novel outcomes, and reduced patient burden. Through the application of new technology in clinical research, next-generation clinical trials can be done effectively with low cost while obtaining high-quality data (Ellar et al.,2017).

Technology advancements that promote immersed treatments include the use of virtual reality technology and comprehensive reality technology. Applied virtual reality utilizes a computer-generated platform to manage prolonged pain and severe pain and anxiety. Virtual reality is shown to have the ability to decrease pain scores in hospitalized patients by 24%. This technology enables patients to have pain-free treatment and increases their compliance (Li et al., 2017). In future clinical research, comprehensive reality technologies will enable regular procedures, improve obedience, and help achieve improved results. Patients would have an easier access and more convenient route of doing procedures or assessment requirement from a clinical trial at the comfort of their own space instead of having to travel to the office. Clinical research professionals can stay more engaged by sending out friendly reminders electronically (text message, email, or other preferable methods of electornic communications). Comprehensive reality technologies help educate research participants about their conditions and treatment plans together with upcoming techniques. Comprehensive reality technology is, therefore, a vital component of inpatient and research participant care.

Technology in the future will revolutionize clinical research by enhancing more use of wearable technological devices by research participants in clinical trials. These wearable technological devices track the research participants' sleep patterns, exercise, and heart rates. The

devices will enable researchers to access real-time and accurate data from the research participants' passively with their consent more easily. In-built sensors placed in phones, clothing, and domestic devices can quickly and continuously gather data from research participants, making the clinical research data collection easy in terms of cost and time used (Majumder et al.,2017).

Miniature, wireless, self-powered, passive sensors comfortable to the research participant can be placed on the research participant's body to improve the data's quality. Temporary digital tattoos (thin layer of films that resembles a tattoo, equipped with digital chips underneath) on research participant bodies can measure drug release to the body, ECG measurement, and fall detection. Wearable devices can provide clinical trial researchers with a clear and detailed picture of a patient's well-being by capturing all research participant exposures lifetime (exposure to risk factors for an ailment or disease) and how they influence a person's health (Bhelkar et al. 2016). During clinical trials, the environment affects the research participants' outcomes. As such, researchers could also assess the environmental impact on the outcome using air-particle sensors and account for these environmental effects in the clinical study outcomes.

Electronic health records help research participants quickly access their records at any time from their homes' comfort without necessarily traveling to the clinic. However, electronic health records are faced with the challenge of upholding transparency during the collection and analysis of research participant data (Kruse et al., 2017). The transparency in this context refers to the direct uses of research participants' data and their anticipations concerning the full band of probable examinations provided. The data's access and utilization will raise many ethical questions about using the data obtained and the extent to which the researchers can utilize the data obtained. Some of the questions expected to emerge include; are the clinical researchers utilizing the data accountable for properly sharing real results to the research participant even if the data's initial

usage is dissimilar? Another question that will emerge is, do the researchers inform the research participant of new disease diagnosis that came up during the clinical trials? Will the research participant be interested to know about the diagnosis? What if the diagnosis turns out to be false negative after the research participant is informed?

Adaptive clinical research updates are activities done to modify the clinical trials to increase or meet expected clinical trial productivity. These adaptive trials can advance clinical experiment accomplishment rates and considerably reduce periods and costs (Li et al., 2020). Electronically captured data is vital in promoting the implementation of adaptive updates in clinical research. Electronic modern technology allows faster analysis of the captured data, allowing adaptive changes to be made promptly. Adaptive clinical trial updates made possible by incorporating modern technology include the addition of research participants to ensure that statistical power is not lost. Statistical power is lost when research participants drop out of clinical trials due to diverse reasons. The dropping out can leave the research study with few research participants who cannot generate data with statistical significance.

Accommodating relocation of research participants is vital in an attempt to meet the preferred treatments at the course of the study due to the collected data. Simply put, once a patient has been identified electronically, technology should be able to compute more powerful randomization, or randomly assigning patients to drugs or placebo – providing each patient with treatment that could strengthen a clinical trial design. Simply speaking, when a randomized trial is conducted properly, randomized trial have the highest level of experimental validity. Proper randomization allows a trial in ensuring equivalent treatment, control groups, and quality control

over the data and timing of the intervention[16]. The use of adaptive updates in clinical trials will reduce the available clinical trial cycle time by propelling whether to continue with the trial or terminate it. The adaptive updates also allow for more relevant analysis time points (Li et al., 2020). Adaptive updates also research participants' exposure to side effects, increasing the research participants' compliance and reducing the dropout rates, thus improving the research participants' retention[17]. Experiments illustrate that 29% of all research participants quit after complying with trials due to their fears about side-effects (Li et. al., 2017).

Technology could improve future clinical trials by connecting research participants and researchers. The connection could promote more effective communication across the clinical research process. There is greater trust and transparency throughout the clinical research trial when there is communication between researchers and research participants, improving research participant engagement and retention. The connection between these two parties can be made through social media platforms. Using technology to better future clinical research is possible by using digital agents to recruit eligible research participants and educate them about the clinical trials (Ellar et al.,2017).

Electronic software can improve research participants' experience during the clinical trials. The digital agent will assess whether the research participant is qualified for any suggested clinical experiments. The agent completes the administrative onboarding process once consent is obtained. Artificial intelligence, together with machine learning, enables the development of intelligent digital agents. In future clinical trials, digital agents will be trained to conduct multifaceted

[16] Retrieved from: https://www.hydroassoc.org/research-101-an-explanation-of-clinical-trials-design/#:~:text=If%20done%20correctly%2C%20randomized%20clinical,and%20timing%20of%20the%20intervention.

[17] Li, L., et al. (2017). Application of virtual reality technology in clinical medicine. *American Journal of Translational Research, 9(9), 3867.*

intellectual tasks, such as defining the research participant's suitability for a clinical trial (Beck et al., 2020). By facilitating fast, well-organized trial finding, and onboarding, these digital agents can quickly and efficiently recruit research participants. The challenge of clinical trial delays due to recruitments will be significantly reduced[18].

The future of clinical research data collection and analysis will be better through the use of modern technology. Clinical experiments history is traced using Blockchain technologies (Benchoufi et al., 2017). Blockchain technology is a decentralized internet platform where "any service or software relying on trusted third parties can be built in a transparent, decentralized, secure "trustless" manner, allowing users to have a high degree of control over autonomy and trust of the data and its integrity". As a result, decentralization applications ensures "traceability, prevents a posteriori reconstruction (beautification of data) and allows for securely automating the clinical trial, and at the same time the technology also ensures fine-grained control of the data, its security, its shareable parameters, for a single patient or group of patients or clinical trial stakeholders" (Benchoufi, et al., 2017). Clinical research networks such as researchers and research participants, together with sponsors, utilize decentralized applications that push and read data to and from the blockchain network. Decentralized data repositories in clinical research can ensure better security of data, ensuring appropriate data privacy and ownership, and preserving clinical experiment data accuracy (Diebolt et al., 2019). This, in turn, lays a solid base for online supervisory authentication of clinical trial results meaning data recorded is up to par with 21 CFR 58.130 (e) ALCOA-C (Attributable, Legible, Contemporaneous, Original, Accurate, Complete) Good Documentation standard. Ownership of research data should employ transparency by remaining in the research participants' hands. It gives research participants more control over their

[18] Beck, D., et al (2020). Increasing access to clinical research using an innovative mobile recruitment approach. *Contemporary clinical Trials communications, 19, 100623.*

collected data. Blockchain and cryptocurrency facilitate the trading of data for payment. A fast and effective system capable of processing large constant streams of data can better the clinical research status.

Human error encountered during data collection could be reduced through electronic data capture. The increased artificial intelligence developments permit immediate data gathering and handling for independent representatives and connected devices (Diebolt et al., 2019). Smooth data management should reduce the traditional data collection disadvantages of an increased amount of period and laborious effort in clinical study management processes. The gathered data could permit researchers to develop opinions on research participant well-being.

Regular clinic visits will soon be reduced in most clinical experiments. Clinic visits can be replaced by incorporating virtual communications, connected wearable devices, and improvements in-home delivery (Park et al., 2018). The AOBiome Stage 2b trial acne study eliminated site visits. The study selected more than eight thousand research participants, but it registered 372 patients for a 12-week study. It also experienced improved inclusivity (more people in more areas regardless of socioeconomic status) in enrollment matched to traditional trials. Research participant-centered connected devices will play a vital role in future clinical research. Connected devices used by research participants like wearable devices, nanotech, extended reality devices, virtual assistants, and bots are precisely utilized to capture data during virtual schedules. Extensive and increased embracing and virtual communication facilitate distant communications between clinicians and their clinical trial research participants (Diebolt et al., 2019).

Advances in the cold cable, three-dimension printing for therapeutic devices, and the distribution drones could promote effective home delivery. It could promote the direct distribution of trial materials to the research participants that would previously have been given to patients

during consistent clinic appointments (Park et al., 2018). The change from site visits to research participants' households should escalate patient loyalty and lessen patient dropout due to the decreased research participants' frequent travels to the clinical research clinics. The cost of conducting virtual study site trials is could be reduced compared to traditional clinical setups, labor-intensive, time-consuming, and costly.

Incorporating algorithms in clinical research will enable easy data analysis from a worldwide, homogenous, safe scientific database. This will approximate the journeys of virtual research participants (participants that are doing clinical trials from the comfort of their own space) through clinical experiments and precisely forecast the trial outcomes (Diebolt et al., 2019). The use of Algorithms in clinical research trials is currently evident in clinical trials like the HumMod physiological model, and existing indication from companies such as Flatiron and Medidata synthetic control arms promotes algorithms use in clinical research.

Chapter 4

4. Results and Discussion

4.1. Planning Phase

The review of the literature revealed that the clinical research planning process is rigorous, time-consuming, and expensive. Researchers have to comply with the regulations and warnings issued by organizations such as the FDA regarding participants' safety and accurate and timely reporting of adverse events (Browning, 2019). The review also revealed the need for regulatory support in enhancing clinical research during the COVID-19 pandemic. The FDA has been relatively quick and responsive in amending its policies and guidelines at the pandemic's dawn, allowing many organizations to implement remote software quickly. However, the concern lies in its ethical and safety concern: does remote deployment prove to be just as safe and confidential as visits done in the office directly (Angeletti, Chatzigiannakis, and Vitaletti, 2017). Unfortunately, there is not much more information available on the impact on full remote visits without the FDA's full support. Diebolt et al. (2019) assert that the full implementation of an entirely virtual visit is the key to advancing clinical trials. The future of clinical trial is already here; however, it would not be fully implemented without a conscious and concerted effort from both industry and regulators to carry the momentum forward.

According to the study by Browning (2019) clinical researchers have to seek the approval of the relevant authorities, which entails meeting the minimum requirements. Bourin (2017) explains that the planning stage presupposes two requirements: the formulation of a clear, precise, and relevant therapeutic question and the certainty that the reply to this question has not already been given in earlier studies. This is in addition to meeting the minimum requirements set by the approving bodies such as the FDA. The current state of clinical research planning and the need to

achieve these goals make it a laborious and expensive process. the conventional face-to-face planning activities prolong the phase and waste a lot of time. For example, a study by Aimee et. al. (2015) revealed that conventional approaches include using newspaper or radio advertisements to recruit participants, mail, or telephone calls are used to conduct follow-up assessments. These processes are costly and time-consuming. Technologies such as mobile phones and social media platforms have the potential to reach a wider audience and are relatively affordable. According to Aimee et. al., (2015), approximately 90 percent of all adults in the US use the internet and own a mobile phone. Moreover, 74 percent of adults in the U.S use have social media pages on platforms such as Facebook, Instagram, and Twitter. Besides, while young people are more likely to be using e-technology older adults are increasingly adopting it in their lives with 77 percent of older adults aged above 65 owning smartphones. As such, these technologies (smartphones and the internet) provide clinical researchers with a wide audience reach that allows them to communicate their study topics and purpose and gather feedback. It also allows them to reach out to millions of people and low costs compared to the conventional newspaper, TV, and radio adverts that are expensive. These also make it possible and quicker to meet the standards set by the regulatory bodies regarding the threshold number of participants that validate clinical research. An example of technology at play in the planning phase is the CTTI's Digital Trials (DHT) Program that was implemented in 2015 to identify and address challenges in planning for and conducting clinical trials. The program focuses on the use of digital health technologies for the collection of objective data (measured directly by the digital technology) in FDA-regulated clinical trials after participant consent (Geoghegan et. al., (2020). The expansion of such programs will help fast-track planning processes and getting regulatory approval.

There is also a need for regulatory bodies such as the FDA to adopt electronic databases that allow researchers to submit required documents electronically instead of the traditional way which is paper based. One of the key issues that could be addressed that had traditionally limited the approval of regulatory bodies is patients' privacy. Particularly, blockchain technologies have been identified as key to ensuring the privacy of patients and data protection. According to Benchoufi, Altman, and Ravaud (2019) blockchain is a secure and distributed data store or ledger ordered records of data that is incorruptible. It allows participants to receive copies of data and validate by consensus the transaction via a strong cryptographic process. The adoption of this technology in providing regulatory approvals will help ensure a fast turnaround for clinical trials to commence. An example of blockchain at work is the development of Embleema, which is a distributed electronic health record system that was developed to grant patients more control over their data and even organizes a data brokerage market place. Another example of clinical trials performed on a blockchain is TrialChain that was implemented over an original Blockchain architecture, where the state of private Blockchain is synchronized to the public Ethereum Blockchain. Such systems make access to required data easy and create the necessary trust needed to validate clinical trials. A key milestone that occurred in the clinical research planning and authorization process was by Pfizer. The pharmaceutical company received clearance from the Food and Drug Administration (FDA) to conduct a clinical trial entirely online (Andrews, Kostelecky, Spritz, and Franco, 2017). This has led to the development of multiple technologies that support direct-to-patient clinical trials, including electronic informed consent systems and remote data collection processes (Andrews, Kostelecky, Spritz, and Franco, 2017). Thus, technology can help assure compliance and obedience as it can send a reminder to the patient

remotely to get them to do whatever assessment required by the study, which necessitates its integration in clinical research.

4.2. The Recruitment Process

This study revealed significant issues with the recruitment process. The conventional method entails placing adverts in newspapers, television, or radio. These platforms are expensive and reach a limited audience. Andrews, Kostelecky, Spritz, and Franco (2017) explain that researchers sometimes have to pay a physician up to $5000 to convince their patients to participate in a clinical trial. Furthermore, these processes make the recruitment process laborious because researchers have to manually analyze the feedback and select participants. Notification of participants is also done manually, which extends the time taken to recruit and conduct the actual study. The lack of tools to facilitate the recruitment of participants and collect data has also limited clinical trials' pace. In some instances, clinical trials have been canceled because of the failure to meet the participant threshold. LaMorte (2016) also revealed significant trust-related issues in recruiting African Americans for clinical trials because they mistrusted research activities. However technology will increase transparency and accountability that will help develop the trust needed to convince African Ameriancs to participate in clinical studies. With the outbreak of the COVID-19 pandemic, most clinical trials have been hampered because of the widespread lockdown and need for patients' isolation. According to Segelov et al. (2020), the Coronavirus has compounded participant recruitment and data collection challenges. While these challenges continue to affect the clinical research process, several studies have revealed that the issues could be solved by adopting technologies that limit close contact with participants.

The review shows that telemedicine and eConsent were the majorly adopted technologies during COVID-19. Telemedicine was typically used for routine checkups to detect adverse side

effects, particularly in Phase I clinical trials (Diebolt et al., (2019). Telehealth was also utilized in measuring objective results by enabling remore data collection during clinical strudies. Teleheath allows patients to update their dietary habits, medications, and other key health paramaters that could be used by researchers to assess the participants' health. eConsent was revealed to be easy to use and implement innovations. The noted advantages of eConsent included enabling communication with research participants through video descriptions and questions to evaluate understanding (Breton, L., S., et al., 2020). The COVID-19 pandemic outbreak revealed that many clinics without any remote software were not prepared for such instances (Breton, Lamberti, Dion, Getz, 2020). Many clinical studies not related to COVID-19 had to either be shut down or put on hold since the FDA was reorganizing its priority towards COVID-19 studies.

Another key benefit of technology in the recruitment process is that it provides access to a large pool of possible participants at a relatively low cost. Researchers could leverage technologies such as mobile phones and social media platforms to create awareness about the research and recruit participants as per the regulations set by HIPAA. Andrews, Kostelecky, Spritz, and Franco (2017) explain that today, the sponsor of a clinical trial can contact potential participants based on their digital data and it is as easy as doing a Google search. There are online services such as TrialX, which is a free service that matches participants to relevant clinical trials based on their health information. It also uses Twitter to match potential research subjects to clinical trials that suit their needs. For example, a study conducted by Yuan and colleagues (2014) used Facebook to recruit participants in a study associated with HIV stigma. The study successfully recruited 1404 adults primarily through Facebook. Moreover, several apps such as the National Library of Medicine Pharmaceutical Product Development's Clinical Trials app are being developed by sponsors and academic institutions to help patients find relevant clinical trials. Thus, these tools

when integrated into clinical research will facilitate the recruitment process, which is very critical to the validation and success of clinical research activities.

4.3. Engagement and Retention

The review revealed that the failure to retain participants is a significant issue in clinical research. Traditional clinical research processes require that researchers engage participants to ensure they commit to the end of the study. However, several issues arise that result in participant turnover. For example, LaMorte (2016) revealed that African Americans may not be responsive in a clinical trial because of historical mistrust. As such, recruiting and retaining them in a study is often challenging. Rosa et. al., (2015) also explained that retention of participants of a clinical study, especially during long follow-up periods after the conclusion of an intervention is often challenging. Traditionally, the process took significant staff effort and resulted in less-than-ideal retention rates. Technologies such as mobile phones, email, social media, and websites have altered how researchers engage participants. These technologies have a wide reach and provide meaningful engagement that is necessary to ensure the retention of participants. Vanaken and Masand (2019) also explain the use of multimedia components to improve participant awareness. Technologies such as eConsent allow researchers to collect individual participant data and metadata that allows for tailored participant engagement

4.4. Data Collection

The way the Coronavirus spread has been a critical issue in the continuance of clinical research. Clinical research often involves interactions with hundreds of participants. Monitoring these participants, collecting data, and reporting adverse events in the wake of the COVID-19 pandemic has been challenging. The study by Majumder et al. (2017) shows that technology could help solve these barriers. Notably, wearable technologies in the future will help researchers to track

the behaviors of the participants and collect vital data on their health. These tools will enable real-time access to patients' data for research purposes—inbuilt sensors in phones. Clothing and domestic devices will also make it possible to collect data and report adverse events remotely, thereby making the clinical research process easy and cost-effective (Bhelkar et al., 2016). An example of technology at play in data collection is the use of the ecological monetary assessment (EMA). The data collection tool is designed to collect data in real-time and deliver interventions for study participants (Rosa, Campbell, Miele, Brunner, & Winstanley, 2015). Researchers can also use wearable devices to collect data. The devices are synced with smartphone apps to facilitate compiling and analyzing vast amounts of data that would have been impossible with the traditional data collection and analysis methods. Electronic health records (EHR) are another tool for data collection. The dissemination of results is a critical aspect of clinical trials. Traditionally, this was done by publishing the results in a peer-review journal or other print publications. Technology has changed how dissemination occurs. Researchers could post results on platforms like Twitter, Facebook, PubPeer, ResearchGate, and Academia.edu.

Conclusion

Overall, this study revealed the need to adopt technology in clinical research to advance it during the COVID-19 pandemic. Clinical research aims to better the researchers' and public members' knowledge of diagnostic methods, diseases, and new treatments or medical devices that can advance patient care. Prevention, diagnosis, prognosis, treatment, and curing disease can be improved using the data generated from clinical research. The data generated is utilized in bettering patient care through the production of products and designing processes. There is a need to place more emphasis on clinical trial studies on human subjects' that are done remotely with technology . Clinical trials are usually done on human subjects to uncover knowledge of new treatments and

behavioral interventions. The treatments usually conducted in human trials usually entail assessing new novel vaccines, nutritional choices, drugs, nutritional supplements, and medical devices. The COVID-19 brought a lot of new perspectives to the clinical research field. The pandemic challenged the clinical research field to have backup plans that ensure clinical trials are carried out effectively should a pandemic occur. The pandemic also brought a new need to incorporate technology in clinical trials to minimize costs and save time.

Clinical research has encountered many advancements across the years, with technology being the primary factor that accelerates clinical research growth. Technology has enabled researchers to carry out clinical trials remotely, thus minimizing costs and saving time. The use of technology, especially in the recruitment process, ensures that there is inclusivity. Research participants' wearable devices have enabled researchers to have real-time and accurate data, promoting clinical research productivity. Despite the growth and milestones that clinical research has achieved, the future of clinical research is auspicious by adapting the new technology in healthcare. Future technologies like artificial intelligence, algorithms, and extended reality models will bring new perspectives to the clinical research field. Thus, there is a need for the health sector stakeholders to develop policies that will ensure the adoption of these technologies to facilitate clinical research and trials during crises such as the COVID-19 pandemic.

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Biographical Statement

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